Megan Columbus: With that, I want to thank you for joining the session. My name is Megan Columbus. I am the communications director in NIH's Office of Extramural Research, and I will be monitoring the session. I have with me today Dr. Sally Amero. She's a peer review policy officer in NIH's Office of Extramural Research. With her today I have John Connaughton. He is with NIDDK. He's in review, as is Dharm Rathore and Kathy Salaita. So welcome to you all. We're going to have a great session on looking at NIH peer review. This session's designed to give you the fundamentals of peer review. Immediately following the session we have a mock study session meeting for you, which is an awfully fun session which we'll show you kind of peer review in action. And so we can get questions on both of these sessions. All right, with that, Sally, why don't you take it away?

Sally Ann Amero: Oh, I'm happy to. Thank you, and I'm seeing we have many messages going on here from people all over the country and even other countries. So, welcome. We are here to explain the NIH peer review process. This is really fundamentally important for you to understand. There are a lot of details we could go into but we decided to focus on just a few topics here and then we will open this for a panel discussion. If we don't get to your questions you can e-mail any one of us, and I'm sure I know that I will answer your questions but I'm sure my colleagues will be happy to do that as well. So here's the fundamental question we're going to address in the next 45 minutes. NIH current receives over 80,000 grant applications a year. That's an awful lot of grant applications and all of us on this call today are involved in this process. Now after what we're going to talk about today only some of those applications result in grants, fellowships, cooperative agreements or contracts. So what's going on here between the receipt of the application and the funding. Well that would be the peer review process. The grant application submitted to the NIH are evaluated on the basis of a peer review process. That strives to be fair, equitable, and timely, and free of bias. So the peer review process, by and large, dictates which applications will be considered for funding and that is why this is so important for you to understand the basics. So we're going to talk about the following five things in the next few minutes. What happens to your application after you or your institution hits the Send button to submit it to the NIH? How are applications evaluated? Who decides whether your application will be funded? What is review integrity? Hopefully you've been hearing some about this in recent years. And what are your action items at the end of this session? Let's start with the first question. What happens to your application? The first stop on the journey of your application is the division of receipt and referral. This is where your application comes in after it goes through grants.gov. Many decisions are made there, such as which of the NIH institutes and centers will consider your application for funding and which study section, which group of reviewers, will evaluate the application in peer review. Rather than going into those details I'm going to refer you to the session that just preceded this one. I watched it. It was really informative and they went into detail in how all those decisions are made. Receipt and referral of your application. So presuming your application is compliant with the format and all kinds of things, it's complete, it proceeds to two levels of peer review. The first level is probably the one with which you are most familiar. That is the initial peer review or

study section level and then it progresses to the National Advisory Council of Peer Review. That one is not quite as well-known, but it's equally important. And assuming that all goes well in those levels of peer review, then funding decisions are made by the director of the NIH institute, or center where your application was assigned to be considered for funding. All right. How are applications evaluated? So we're moving on to the next question. Initial peer review evaluates applications for the following things: scientific and technical merit of the work proposed, the overall impact that the study the work proposes is likely to have on the field in question, appropriate justification for human subjects' protection, inclusion across the lifespan, and vertebrate animals. This process is managed by NIH Scientific Review Officers, or SROs. Now there are about 500, 600 SROs at the NIH, so this is a big operation. And you need to find your SRO in your study section. Next slide? Now who does the evaluating? So the scientific review officers manage the review process but they cannot get involved in the actual evaluations because that would be a conflict of interest. So we bring in mostly nonfederal but extramural scientists to conduct the peer reviews and do those evaluations. On a yearly basis we bring in over 27,000 reviewers through NIH to do this big operation. They're recruited on the basis of expertise. We manage their conflicts of interest. We try to balance representation on the basis of geography, gender, minorities, stature, senior, junior and so forth, as well as their stature in the field. So in order to be a reviewer they have to have demonstrated expertise in the field that's being reviewed. That can be done through publications, grants, recommendations and so forth. For each application, at least three of those qualified reviewers are assigned to provide an in-depth assessment of the application to provide written critiques and criterion scores. These are numerical scores given to each of the review criteria. They also provide .. . I'm sorry. Your pictures are over my slides. They also provide preliminary overall impact scores. Now the assignment, the three reviewers, three or more, who are assigned to your application, and their conflicts of interest are strictly confidential, so you cannot find out that information unless there's been a breach of review integrity. Next slide? So at the review meeting for each application members with conflicts of interest are asked to leave the room. Now there are some conflicts of interest that are so severe that we would not have the reviewer on the same study section where that application is being reviewed. So either we'd have to remove the reviewer or we'd have to put the application elsewhere. But the majority of the conflicts and grant reviews are what we call out of the room where the reviewer simply is not present for the discussion and evaluation of the particular application that's creating the conflict. The assigned reviewers - that's three or more out of the panel assigned to the application - present the strengths and weaknesses to the rest of the panel. The eligible members, and by that, we mean people without conflicts, then join the discussion. The chair of the panel summarizes the discussion, the assigned reviewers provide their final scores, and then all the members provide final scores privately. Once the scoring is done there are a number of other issues that the panel is asked to discuss such as the budget, authentication of key resources and a few others. So rather than spending a lot of time here on what happens at the study session I'm going to invite you to stay tuned after this session to watch the live mock study section where we have actors, we have NIH staff who are actually going to act out what a study section meeting would

be like. So let's talk a little bit about the review criteria. I urge you to become familiar with the review criteria that are going to be used in evaluating your application. They're not all the same, and so it makes sense. When we were in school we would ask what's going to be on the test? Well it's the same thing here, but how are you going to be evaluated? One simple answer is that for all applications the umbrella consideration, the umbrella evaluation, is for overall impact. Now overall impact is defined differently for different types of applications. For example, for research grant applications overall impact is defined as the likelihood for the project to exert a sustained, powerful influence on the research field or fields involved. Now obviously that definition would not be appropriate for, say, a fellowship application, where we're talking about training. And career development and things like that. So the definition of overall impact does change, depending on the type of application. So how can you find out, the review criteria? Well, by law we have to provide the review criteria in section five of the funding opportunity announcement that you use to submit your application. So we don't change them after your applications are in. We use the review criteria stated in the funding opportunity announcement. So you need to pay attention to that when you're writing your application. We talked about the fact that the review criteria can differ for research. For example, we asked about significance, approach, innovation, investigator and environment. Those are different for say, fellowship applications or post-doctoral applications where we're talking about the mentor and we're talking about the training plan and so forth. Despite all that variability, we can boil down different categories of review criteria for all applications. And you'll see this in your funding opportunity announcement. Some criteria are called scored because they .. . Each of the criteria is assigned a numerical score, a criterion score, and each of those criteria can affect the overall score for the entire application. Then there's the category that's in the middle, and these are called additional review criteria, because they do not receive criterion scores, but they can affect the overall impact score. And finally, we have a category of considerations. These are the ones that are brought up in discussion after the scoring is over because they do not affect the score and they do not get individual criterion scores. I've provided some additional information in the appendix slides for you to look at later. All right, so I've talked a lot about criterion scores, overall impact scores, and let's just review the NIH scoring system. Reviewers give numerical scores. There are a few exceptions, that I'll talk about in a minute. But by and large the numerical scores range from one, which is exceptional, to nine, which is poor. That's our range. These .. . That range .. . These are whole integers and that range is used for both the individual criterion scores and the final impact scores. And you can see the various adjectival .. . I'm sorry, I just saw the comment in the chat here. I think some of us do remember the 100 to 500 score range. Where was I? An important point to make is that the criterion scores are not used in factoring or calculating the overall impact scores. The criterion scores are simply there as indicators of the assigned reviewer's emphasis, if you will. Which of the things did they think were most meritorious, where did they find the weaknesses. But the final impact score is calculated from final impact scores given by all of the reviewers who did not have conflict. Next, please? Okay. Okay, so as I just said all the members who do not have conflicts vote their final impact score after the discussion has been closed. The final

impact score is calculated by averaging all the reviewers' scores, multiplying by 10, so the final range of scores is from 10 through 90. Now, because we run 2,700 review meetings a year, we use a percentiling mechanism to average, to compare, the scores - shouldn't say average. To compare the scores from one study section to another. So on some reports of the outcome of review you might see a percentile number as well. Okay. So 10 would be the highest impact. 90 is the lowest impact. Next, please? Except there is another process that we use in most of our review meetings. This is called the streamlining process. This process was developed to allow the study sections to focus the discussion on the more meritorious applications and really on the applications that are in between the most meritorious and the least meritorious so the decision was made some years ago, that the least meritorious applications are those that are probably not going to be considered for funding and therefore the study sections would focus on those that are more likely to be considered for funding. Those are designated Not Discussed, ND. That's not North Dakota, that's Not Discussed. The panel makes a decision at the beginning of the meeting about which applications will not be discussed further but I want everyone to understand that before the study section meets there were three assigned reviewers or more who provided preliminary criterion scores, preliminary impact scores, and written critiques. So it's not correct to say that they weren't evaluated. The correct designation, the correct way to think about this is that they were not discussed by the panel. I want you to emphasize also, I want you to remember that this requires the full concurrence of the entire study section. One member, one reviewer in that panel can say, "I want to discuss it." And then it has to be discussed. And if it's discussed, then it gets a numerical score. There's no guarantee that once it's discussed, it's going to fare any better but that's the way this works. At end of that process there will be a summary statement. There will be a written outcome of the review, and for not discussed applications those summary statements will contain the written critiques from the assigned reviewers and the criterion scores. So for these applications, the scores can range from 10 to Not Discussed. Okay. Next slide? So the outcome of the review process for initial peer review is a final impact score which typically is released within three days after the meeting is concluded. Might be sooner. But they're pretty good about that one. The summary statement is a written outcome of review with the critiques, with the criterion scores, with the bunch of codes. And those are typically released within four to eight weeks after the meeting. Where can you go to find these? Check the eRA Commons, and you will find that information when it's available. Next slide, please? All right. So let's say peer review is done, initial peer review. Now something happens here about your points of contact at the NIH. So at this point you really should be interacting with your NIH program official rather than your scientific review officer. That person can advise you on a number of things, whether to submit Just-in-Time information, how to resolve human subject, vertebrate animal, inclusion problems, and to consider the options at your disposal. You might be advised .. . You might consider submitting a new application. You might revise and resubmit the application that just completed peer review or you could appeal the review outcome. That's a fairly complicated process that your program officer could describe to you. Next, please. All right, so that's the first level. Now, let's talk about the second level of peer review which is the NIH advisory councils. These are typically

composed of a broad and diverse membership. They typically have public members or disease advocates on them. Awards cannot be made without the council's approval. The procedures vary across the ICs, so I'm not going to go into those procedures at any great length. Now each council is chaired by the director of the institute or center and is advised by their staff. Next, please? So what do these council members advise the director about? Well, they talk about priority areas for research, policy issues, concept clearance, funding priorities but for your purposes, they recommend applications for funding. They also consider appeals of initial peer review that cannot be resolved any other way. Next, please? As we talked about the IC director makes the final funding decisions. Those are based on a number of factors. The outcome of initial peer review is certainly an important consideration, but not the only one. For example we have special initiatives where mandates - Congress mandates that we study certain diseases or certain problems and that is factored in the recommendation of the council and of course if we have money. That's always important if we have money to spend. Next, please? Oh boy. So what is review integrity? Each of us has a responsibility to uphold peer review integrity, and a violation could lead to many serious consequences. I'm going to ask that you log in on Thursday and listen to discussion with Mike Lauer on review integrity and mistakes you don't want to make. So let's go to the next slide, please. There are two topics here I want to talk about which are conflict of interest and confidentiality. So please be advised that each reviewer must sign two conflict of interest certifications and failure to declare them can result in penalties. So here you see the certification language that they attest to. And next? Confidentiality has become front and center lately because we had some breaches of confidentiality that have turned out to be very very serious. I'm going to assume that by and large, the audience today is applicants and I must emphasize to you that contacting a reviewer to ask about the review of your application to provide more data, to bribe them, to threaten them, to just strictly forbidden and it will get you in a world of trouble so don't even think about it. Now let's say you're at a meeting and you're walking down the aisle of a conference when we're all allowed to travel again, and you run into a reviewer it's certainly fine to say yes, hi, but do not discuss your application. Okay, next. So what are your action items. So you have responsibilities here. I urge you to join the NIH Guide table of contents. This is where you will see new funding opportunity announcements. You will see new policy notices. Read Section V of your funding opportunity announcement, uphold review integrity, and stay tuned for the mock study section. So with that I'm going to open this up to a panel discussion.

Megan Columbus: All right, so as we're getting our panel on the screen. Thank you so much, Sally, that was a great presentation. So as you can imagine we have all kinds of questions here for you and the others. Can you talk a bit about how peer reviewers are trained? Or any of the other panel members, for that matter? Please remember to take yourselves off mute.

Kathy Salaita: I can take that, Megan. Each SRO might have their own approach for training but, I think in general all of us take it very seriously and I know for myself, I'll do a training teleconference or a video teleconference or video conference now with the reviewers and actually schedule a couple different sessions, so we make sure we get as many reviewers as we

possibly can. We have training materials. Many training materials available online through NIH OER. We have reviewer sources. We also -- um, I will also send e-mails to the reviewers with some training guidance periodically throughout the process. So we never let our reviewers go into a study section meeting unprepared.

Dharm Rathore: And I can add a few things: So we do conduct review of orientation sessions, and if it's in response to a [Indistinct] happening within a review, or within an institute outside of CSR, then we will even have programs staff will attend those sessions, for the most part. And reviewers will frequently ask questions about getting some clarity about FOA, and we try our best, that if there is a little bit of ambiguity in the FOA itself, then the benefit of doubt goes towards the applicant. And they don't ding the applicant because the FOA itself was not very clear.

Megan Columbus: Great, thank you so much. What about -- How do program officials work with SROs, and might one program official work with many SROs?

John Connaughton: Yes, so this is John. I can take this. So at NIDDK, SROs and program officials will work together on initial drafts of funding opportunity announcements for clarity especially, clarity in the review criteria. Program staff may provide some suggestions into potential reviewers based on their understanding of individuals' scientific expertise. SROs may or may not consider those. They may consider them a starting point to identify additional reviewers for the roster on the committee. That's evaluating those applications.

Megan Columbus: Right, thank you so much, John. What about resubmissions? We have a number of questions about resubmissions. Do they automatically go to the same study sections? What do you do if you don't want it to? Why do some of the same study sections your resubmission does either far better or far worse than the original application even when you addressed the reviewer comments.

Kathy Salaita: Megan, I can answer part of that or at least start with your last one there, which I think I saw pop up a couple of times about why does it sometimes get worse? Each application when it comes in is reviewed on its own merit, and while response to the prior review is one of the considerations we ask reviewers to look at, it's certainly only one thing that influences the review. And the application's score. And your application might be assigned to a whole new set of reviewers who see a different set of concerns with the application and their scoring is going to be different.

Megan Columbus: And that's even if it goes to the same panel, Kathy?

Kathy Salaita: Even if it goes to the same panel it can have a different set of reviewers. Our reviewers are volunteers. So a reviewer available at one meeting might not be available for a second, but we also don't .. . we don't make a commitment that we assign the same reviewers to an application.

Megan Columbus: Thank you. What about intellectual property and unpublished data that are in applications? How do we protect that information?

Sally Ann Amero: I'll take that one. So each .. .

Megan Columbus: Thank you, Sally.

Sally Ann Amero: .. . Each reviewer must sign a legal document before they ever see the applications. It's called a confidentiality certification. And that was part of the language on that slide that we looked at right at the end of the presentation but they vow, under penalty of perjury, that they will not divulge information that is confidential in the meeting or in the applications. Now we have had some breaches and we have pursued those people with the full extent of our legal capabilities.

Megan Columbus: Thank you. Just back to the resubmission question: Will the summary statement of the initial submission be sent to the new reviewers along with the resubmission materials?

John Connaughton: Yes.

Kathy Salaita: Yes.

Megan Columbus: Great.

Kathy Salaita, Yes, yes.

Sally Ann Amero: Not the application.

Kathy Salaita: No. The prior summary statement is available to the reviewers.

Sally Ann Amero: But not the prior application.

Kathy Salaita: Correct.

Megan Columbus: So, can a study section member who's in conflict because they're from the same institution, can they access the application that they're in conflict with?

John Connaughton: No.

Kathy Salaita: No.

Sally Ann Amero: No.

Kathy Salaita: No, the system bars them from seeing materials.

Sally Ann Amero: They used to be able to but we put an end to that.

Megan Columbus: Great. So another question on a different topic, we have a fair number of people interested in letters of support. And how letters of support are used and who they're actually needed from. Is it all key personnel? Is it others? What's your advice?

Dharm Rathore: I can jump in. So [Indistinct] you know, if you have people from your own institution, let's say you have a postdoc. You don't need letter of support from a postdoc. If you have a faculty member from the same department he or she is going to get a salary support in there plus lab support you don't need a letter of support. But if you have essentially a subaward

in there, for example if you are at Hopkins and you are collaborating with University of Maryland, then it's good to have a letter of support and the letter of support should clearly indicate what's going to be the role of the support writer. Are they going to provide you intellectual input? Are they just going to provide you with reagents? Are they going to help you with data interpretation, and what all. And that would really help us, as well as the review panel, in making a determination about the utility of that letter.

Megan Columbus: Great, thank you, Dharm.

Sally Ann Amero: Some FOAs, some funding opportunity announcements specify that certain letters of support are required. And if they are missing, the application will not be accepted, so read the FOA carefully.

Megan Columbus: And that's good advice across the board. Thank you, Sally. Going back to Sally, you had mentioned breaches of confidentiality. Folks want to know, what if anything changed in response to them?

Sally Ann Amero: Oh, well, we're going to talk a lot more about that on Thursday and the mistakes you don't want to make. And I hope that you've found the presentation last year that Dr. Lauer and I did where he gave a lot of these stories on the what did we call that? The masterclass. So there have been consequences. Some people have been fired by their employers once this became known. We have removed a number of people from the peer review process, so they can no longer interfere or breach confidentiality. We have referred a couple individuals for suspension and debarment. There's a range of consequences that could ensue.

Megan Columbus: All right, thank you, Sally. How does NIH address or prevent reviewer bias towards applications related to institutions? Excuse me. Either they're minority-serving, or maybe they're Ivy League or PIs. I mean, how are we addressing bias. An easy question, of course.

Sally Ann Amero: You stumped the panel. So we did an analysis some years ago on the impact of each criterion on the overall impact score. And out of them all, the one with the least influence on the overall outcome was the institution. So I'm not sure that we have assessed bias in that way. But I know that it turns out to be the one with the least influence.

Megan Columbus: Nice, thank you, Sally. How about switching to a little bit about .. . Sorry. Percentiles. So is a percentile for funding by study section, or across institutes, you know, what does it mean, 1/10 percent? It means 10 percent of the applications in the study section are funded, like, what does it mean?

John Connaughton: So, individual ICs will publish their paylines, so some ICs will fund up to the 16th percentile, for R01s from established investigators. They make fund up to 25 percent for early stages and new investigators, and for the first resubmission of an RO1 there could be an intermediary percentile payline, like 19th percentile. Those are the numbers that are currently on the NIDDK website.

Megan Columbus: So thank you John, but the percentile itself is .. . It's normalizing across study sections, right?

John Connaughton: Yes.

Kathy Salaita: Correct. Correct.

John Connaughton: Some percentiles are for the individual study section. They'll have a percentile based on the prior two rounds of applications that came into that particular study section. Others may be percentiled against .. . across the entire NIH percentile base. And in a lot of RFAs issued by ICs, there are no paylines. Fellowships may not be percentiled. K applications may not be percentiled. It depends on the IC.

Megan Columbus: Thank you. Why would a funding decision get pushed to the next fiscal year, right? If somebody did really well. Why might it change? And not get funded immediately? And this is a little bit outside of peer review.

John Connaughton: Applications that come in during the winter, so late January, February, March, are reviewed during the summer and go to October council, which is the next fiscal year. So that group is not really being bumped to another fiscal year. That's the fiscal year that their applications have come into for funding and it's the first council round of the new year. The remaining, the January council, and then the May council. Some applications coming in for Oct cycle may be funded in the prior year dollars. So it has a very much a programattic question, but that's generally how you know, how it works. At least in terms of funding. Program can .. . May move an application to the following fiscal year as well. So they have a lot of flexibility, I think on that end of .. .

Megan Columbus: Thanks, John. So there's a number of reasons why that can happen. Right? A couple people asked about what happens if there's no percentiles? How do they understand what their impact score means?

Sally Ann Amero: Well, as we said, it's important to first, get your summary statement and read it very carefully. Probably buy a box of chocolate and take a day or two to think things over. But then have a conversation with your program officer who can explain where that impact score .. . What that impact score means in the context of that review, the RFA, that funding opportunity and so forth.

Megan Columbus: Thank you, Sally. Other questions. There are a lot of questions here, some of which we've actually captured already in some way, and so .. . What if there's a comment in your application that suggests the use of a specific technique that few people have mastered and one panelist is an expert. Can you contact this person?

Sally Ann Amero: I'm sorry, could you repeat that?

Megan Columbus: It seems to be asking about whether it's appropriate to contact a member of the panel because there's not a lot of expertise about a particular technique in the application.

And I believe the answer is, it's never okay to reach out to a member of the panel who's reviewing your application. Would that be true?

Kathy Salaita: It would be very true.

Megan Columbus: I felt that might be the case.

Dharm Rathore: Megan, I think there's a nuance in that question. So what they're asking is, once the review is over and they look at the roster and the summary statement, and the summary statement is talking about you should pursue this particular technique. On the roster itself, they realized that there is one person who is an expert in that technique. So is it okay for them to go and talk to that expert after the review. And it's a very slippery slope, as we all know, so I would advise that they either try to find another person who can serve as an expert in that area, because you will have to walk a very fine line. You absolutely cannot talk about the review with that reviewer because we really tell our reviewers that if an applicant will contact you and want to talk to you about what happened in the meeting then you can get in touch with us and it's never a good idea for an applicant to discuss anything with a panel member, with respect to their application.

Sally Ann Amero: So for example, back to the question on resubmissions, let's say your application is reviewed, the review is over. You contact a reviewer for help with the technique, and then your resubmission comes back and it can't go to that reviewer again. That reviewer has had input into your project. So tread very carefully here.

Megan Columbus: All right. So we only have one more minute left, and I know that people have lots more questions because I can see all the questions that are coming in. I do want to tell people that we have review staff all over this conference, and so virtually every institute booth you there has review staff helping to staff it. We have a central ask a review officer booth but really go out, and we have questions. I mean we would love to talk to you about it and it's a lot easier to actually have a conversation than to have a question and answer. And so please reach out to folks. I want to thank everybody on this panel. This has been really very helpful. Your feedback to our attendees is very important and so there's a feedback form on the screen where you came from to get to this session. I'd love to hear what you thought of this session. And of course when you finish the conference, we'd love to hear how it went overall. But thank you all for joining us. This has been lovely. And have a great conference. Okay. Goodbye.

Kathy Salaita: Thank you!

Dharm Rathore: Bye everyone.

Sally Ann Amero: Bye!